

Applicants: Matthias G. von Herrath
Application No.: 09/336,672
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In the Claims

Please cancel claims 42-44, 47-53, 56, 57, 64 and 65 without prejudice .

Please amend claims 40, 45, 54 and 62 to read as follows:

40. (Amended) An immunomodulating composition for treating a condition or autoimmune process associated with autoimmune diabetes, said composition comprising one or more nucleic acid construct encoding GAD self-antigen and IL-10 in a pharmaceutically acceptable carrier.

45. (Amended) The composition of claim 44, wherein the nucleic acid construct further comprises a regulatory element operatively linked to nucleic acid encoding the self-antigen or the IL-10.

54. (Amended) A method for treating autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid construct encoding GAD self-antigen and IL-10 in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the IL-10 in the subject treats the autoimmune diabetes.

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FM 62. (Amended) A method for treating an autoimmune process associated with autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid construct encoding GAD self-antigen and in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the IL-10 in the subject treats the autoimmune process associated with the autoimmune diabetes.

Please add the following new claims 69-83:

FB 69. (New) An immunomodulating composition for treating a condition or autoimmune process associated with autoimmune diabetes, said composition comprising one or more nucleic acid construct encoding an insulin B-chain self-antigen and a cytokine selected from the group consisting of IL-10, IL-4, and a combination thereof, in a pharmaceutically acceptable carrier.

70. (New) The composition of claim 69, wherein the autoimmune diabetes is type I diabetes.

71. (New) The composition of claim 71, wherein the nucleic acid construct further comprises a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

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72. (New) The composition of claim 72, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

73. (New) A method for treating autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid construct encoding insulin B chain self-antigen and a cytokine selected from the group consisting of IL-4, IL-10, and a combination thereof, in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the cytokine in the subject treats the autoimmune diabetes.

74. (New) The method of claim 76, wherein the subject is a human.

75. (New) The method of claim 76, wherein the nucleic acid construct further comprises a regulatory element operatively to the nucleic acid encoding the self-antigen or the cytokine.

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76. (New) The method of claim 78, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

77. (New) The method of claim 71, wherein the treatment comprises controlling the blood sugar of the subject.

78. (New) A method for treating an autoimmune process associated with autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid construct encoding insulin B-chain self-antigen and a cytokine selected from the group consisting of IL-4, IL-10, and a combination thereof, in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the cytokine in the subject treats the autoimmune process associated with the autoimmune diabetes.

79. (New) The method of claim 78, wherein the subject is a human.

80. (New) The method of claim 78, wherein the nucleic acid construct further comprises a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

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81. (New) The method of claim 80, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

82. (New) The method of claim 80, wherein the treatment comprises induction of T-cells reactive to the self-antigen.

83. (New) The method of claim 80, wherein the nucleic acid construct is naked DNA.
